



BILLING CODE: 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2018-0001]

Notice of Request for Revision to and Extension of Approval of an Information Collection;  
Virus-Serum-Toxin Act and Regulations

ACTION: Revision to and extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request a revision to and extension of approval of an information collection associated with the Virus-Serum-Toxin Act and regulations.

DATES: We will consider all comments that we receive on or before [INSERT DATE 60

DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0001>.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2018-0001, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0001> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue

SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on the regulations related to the Virus-Serum-Toxin Act and regulations, contact Dr. Donna Malloy, Section Leader, Operational Support, Center for Veterinary Biologics Policy, Evaluation, and Licensing, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737-1236; (301) 851-3426. For copies of more detailed information on the information collection, contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851-2483.

#### SUPPLEMENTARY INFORMATION:

*Title:* Virus-Serum-Toxin Act and Regulations.

*OMB Control Number:* 0579-0013.

*Type of Request:* Revision to and extension of approval of an information collection.

*Abstract:* Under the Virus-Serum-Toxin Act (21 U.S.C. 151–159), the Animal and Plant Health Inspection Service (APHIS) is authorized to promulgate regulations designed to prevent the importation, preparation, sale, or shipment of harmful veterinary biological products. These regulations are contained in 9 CFR parts 102 to 124.

Veterinary biological products include viruses, serums, toxins, and analogous products of natural or synthetic origin such as vaccines, antitoxins, or the immunizing components of microorganisms intended for the diagnosis, treatment, or prevention of diseases in domestic animals.

APHIS issues licenses to qualified establishments that produce veterinary biological products and issues permits to importers seeking to import such products into the United States.

APHIS also enforces regulations concerning production, packaging, labeling, and shipping of these products, and sets standards for the testing of these products. These regulations ensure that veterinary biological products used in the United States are not worthless, contaminated, dangerous, or harmful.

To help ensure that veterinary biological products used in the United States are pure, safe, potent, and effective, APHIS requires certain information collection activities, including, among other things, establishment, personnel qualification, and product licenses; product permits; packaging and labeling; requests for materials; shipment authorizations; product and test reports; preparation and usage requests; development and field study summaries; stop distribution and sale notifications and inventories; due diligence petitions; and recordkeeping.

The information collection activities above are currently approved by the Office of Management and Budget (OMB) for the Virus-Serum-Toxin Act and regulations under OMB control numbers 0579-0013 and 0579-0460. After OMB approves this combined information collection package (0579-0013), APHIS will retire OMB control number 0579-0460.

We are asking OMB to approve our use of these information collection activities, as described, for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

- (1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;
- (2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

- (3) Enhance the quality, utility, and clarity of the information to be collected; and
- (4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; e.g., permitting electronic submission of responses.

*Estimate of burden:* The public burden for this collection of information is estimated to average 0.001 hours per response.

*Respondents:* Veterinary biological product developers and producers, foreign government officials, State government officials, and private individuals.

*Estimated annual number of respondents:* 405.

*Estimated annual number of responses per respondent:* 737,790.

*Estimated annual number of responses:* 298,804,802.

*Estimated total annual burden on respondents:* 91,000 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 24<sup>th</sup> day of January 2018.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.  
[FR Doc. 2018-01576 Filed: 1/26/2018 8:45 am; Publication Date: 1/29/2018]